

### **REMARKS**

This responds to the Office Action dated December 22, 2004. Claim 14 is amended, and no claims are canceled or added. Thus, claims 14-46 remain pending in the application. Of these pending claims, claims 14-17 are currently under consideration, and claims 18-46 currently stand withdrawn.

#### **Information Disclosure Statement**

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Supplemental Information Disclosure Statement filed on September 27, 2004, marked as being considered and initialed by the Examiner, be returned with the next official communication.

#### **Telephone Interview Dated Feb. 25, 2005**

Examiner Jeffrey Jastrzab called Applicant's attorney, Marvin Beekman, on February 25, 2005 in response to a request from Applicant's attorney for clarification of the rejection as it applied to the Alt et al. reference (US 5,725,559). The Examiner is thanked for conducting the brief interview to clarify the rejection.

The Examiner interprets Alt to provide a first module for receiving a user selection of a clinical rhythm and a second module for receiving a user-provided selection to modify at least one detection enhancement. With reference to Alt, the Examiner provided an example where a defibrillation function is restored, and considers the restoration of the defibrillation function to constitute a user-provided selection of a clinical rhythm. In view of the restored defibrillation function, the Examiner also considers that a change in the sensing / detection parameters is inherent for the restored defibrillation function, and asserts that this is a detection enhancement associated with the restored defibrillation function. During the interview, the Examiner supported his position, referring to "the full range of features" supported by the device software and the ability of the programmer to "limit the range of features according to the selected upgrade level" to support the rejection (Col. 8 lines 58-63).

Applicant's attorney did not argue for the allowance of the claims during the interview since the purpose of the interview was to clarify the rejection with respect to the Alt reference. Thus, no agreement was reached as to the allowability of the claims.

Applicant's attorney believes that this fairly characterizes the Examiner's position with respect to the Alt reference. The Examiner is requested to review this record of the interview, and provide clarification of his position appropriate.

§102 Rejection of the Claims

Claims 14-16 were rejected under 35 USC § 102(e) as being anticipated by Alt et al. (U.S. Patent No. 5,725,599) as set forth in the previous Office Action dated June 25, 2004. Applicant respectfully traverses for at least the following reasons.

Claim 14 recites a programmer for a user to program a pulse generator to detect a clinical rhythm and selectively apply therapy for the detected clinical rhythm. The programmer recited in the claim includes a first module and a second module.

The first module receives a user-provided selection of a clinical rhythm. The clinical rhythm is associated with one or more available detection enhancements. The first module is preprogrammed to provide a selection of at least one detection enhancement from the one or more available detection enhancements that are associated with the clinical rhythm. The second module receives a user-provided selection to modify the selection of the at least one detection enhancement provided by the preprogrammed first module.

With respect to the previously-presented claim 14, Applicant is unable to find a showing or fair suggestion of detection enhancements that are associated with a selected clinical rhythm and are available for selection, a first module preprogrammed to provide a selection of at least one detection enhancement that are associated with the clinical rhythm, and a second module to receive a user-provided selection to modify the selection of the at least one detection enhancement provided by the preprogrammed first module. Detection enhancements are used in implantable cardioverter defibrillator therapy to reduce the incidence of inappropriate shocks (page 1 lines 15-16), and are sets of rules for determining when to deliver shock therapy (page 1 lines 22-23). The first module, with the preprogrammed selection of at least one detection enhancement, lets less sophisticated users rely on the expertise of the engineers and physicians

who designed the defibrillator system; and the second module, with the ability to receive a user-provided selection to modify the selection of the at least one detection enhancement provided by the preprogrammed first module, provides the experienced physician with the ability to manipulate the values of parameters associated with particular detection parameters (specification at page 6 lines 3-7).

Applicant amended independent claim 14 to further clarify the recited subject matter, and intends that the recited subject matter after this amendment is coextensive in scope with the recited subject matter before this amendment. In the previously presented claim, available detection enhancements are associated with the clinical rhythm, the first module is preprogrammed to select enhancement(s) from the available enhancement(s), and the second module receives a user-provided selection to modify the selected enhancement(s). The amendment further clarifies that available detection enhancements associated with the clinical rhythm are available based on the selected clinical rhythm and are for selection by the user to add specificity for determining when to deliver shock therapy for the selected clinical rhythm. The amendment also provides further clarification that the detection enhancement(s) selected for modification using the second module are provided by the preprogrammed first module and are modified to other detection enhancement(s) from the available detection enhancement(s) that are associated with the clinical rhythm.

Applicant respectfully submits that the recited programmer is not shown in the Alt reference. Should the rejection be maintained, Applicant respectfully requests the Examiner to apply the Alt reference against the language of the claims and clearly identify the portions of Alt relied upon to support the rejection so that Applicant can judge the propriety of continuing in the prosecution. (37 CFR §1.104(a)(2)).

Claims 15-16 are dependent on claim 14. These dependent claims recite additional features, and are believed to be allowable at least for the reasons provided with respect to claim 14. Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested.

Applicant respectfully traverses the Examiner's assertion of inherency with respect to the user-provided selection to modify the selection of the at least one detection enhancement, and respectfully submits that that the Examiner has not provided a *prima facie* case for inherency. In

relying upon the theory of inherency, the Examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the reference. §MPEP 2112.

Applicant does not admit that Alt provides a showing or fair suggestion of programmable detection enhancements for a restored function (e.g. defibrillation function). However, even if the restored function has programmable detection enhancements, Applicant respectfully asserts that it does not necessarily flow from Alt that the detection enhancement(s) are associated with the rhythm, that there is preprogramming to select detection parameter(s) for the rhythm, and that the detection parameter(s) selected by preprogramming are capable of being modified by a user-provided selection from the detection enhancement(s) associated with the rhythm. Alt indicates that functions which have customarily been made programmable in conventional implanted device to allow changes, selections, activation or deactivation by the physician would not be affected (col. 4 lines 41-45). Applicant's specification indicates that detection enhancements were previously treated as separate items on a laundry list of possible enhancements, such that physicians either ignored the enhancements or struggled with programming the detection enhancements into the patient's defibrillator (specification at page 1 lines 25-30). Thus, even if the customary programming functions referred to Alt includes programming detection enhancements, Applicant respectfully asserts that it is not inherent that Alt has programming by user-provided selection of detection enhancement(s) from detection enhancement(s) associated with the clinical rhythm, as provided by the recited claim language.

§103 Rejection of the Claims

Claim 17 was rejected under 35 USC § 103(a) as being unpatentable over Alt et al. (U.S. Patent No. 5,725,599) in view of Nelms (U.S. Patent No. 4,323,074). Applicant respectfully traverses the rejection at least for the following reasons.

With respect to dependent claim 17, Applicant is unable to find, among other things, in the combination of Alt and Nelms a fair suggestion of a module for receiving a user-provided selection of a clinical rhythm, where the clinical rhythm is associated with one or more available detection enhancements, and a module for receiving a user-provided selection to modify the selection of the at least one detection enhancement, as recited in the base claim 14. Furthermore, with respect to dependent claim 17, Applicant is unable to find, among other things, a first screen that provides a capability to activate the at least one detection enhancement which is seeded with at least one parameter, and a second screen that provides a capability to change the at least one parameter for the at least one detection enhancement, as recited in the claim. Withdrawal of the rejection, and reconsideration and allowance of the claims are respectfully requested.

Consideration of Withdrawn Claims

As provided in Applicant's previous response to the restriction requirement, Applicant believes that at least independent claim 14 is generic to the species identified by the Examiner. In accordance with 37 CFR 1.141, Applicant respectfully requests consideration of the withdrawn claims upon the allowance of a generic claim.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6960 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

JAMES O. GILKERSON ET AL.

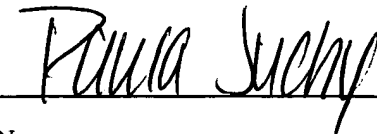
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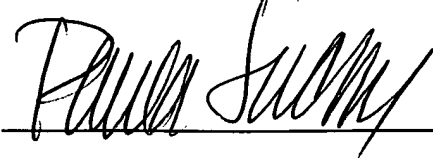
Date 3-10-05

By   
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11 day of February, 2005.



Name



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